

A Silver Alginate-Coated Dressing to Reduce Peripherally Inserted Central Catheter (PICC) Infections in NICU Patients - a Pilot Randomized Controlled Trial



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Abstract

Background: Although PICC provide necessary vascular access for nutrition and medications their use is associated with local and systemic infectious complications. Ionic silver has broad antimicrobial activity and is used in silver alginate dressings to reduce PICC infections in adult ICU patients. **Objective:** The study evaluated the safety and efficacy of a silver alginate-containing dressing to reduce PICC infections in NICU patients in preparation for a larger multi-center efficacy trial. **Methods:** Vanderbilt NICU patients were randomized 3:1 to either receive or not receive a silver alginate and maltodextrin containing patch (Algidex™, DeRoyal®, Powell, TN). The patch was placed under the standard transparent retention dressing at the PICC exit site at the time of PICC insertion and was replaced with every dressing change at least every 2 weeks until the PICC was discontinued. All study infants were monitored for adverse skin reactions and for PICC-associated bloodstream infections. **Results:** A total of 75 total number PICC lines were 89 in the patch group and 29 in the control group. Despite computer randomization, subjects with the patch had a statistically significant lower birth weight compared to the control subjects. The median birth weight was 1,330g in the patch and 2,450g in the control group (p=0.0051). The median age at PICC placement was 5 days in the patch and 4 days in the control group (p=0.38). The median number of PICC days was 13 in the patch and 10 in the control group. (p=0.11). No adverse skin reactions were noted. PICC infections occurred in 12% of PICC lines with the patch (7 per 1,000 PICC days) versus 17% (11 in 1,000 PICC days) in the control group. When adjusted for birth weight, the rate of infection with patch was 0.45 (95% CI: [0.14, 1.38] times as high as in the control group. **Conclusion:** This pilot trial suggests that silver-alginate coated dressings are safe and possibly effective in reducing PICC infections. Based on the results of this pilot study, a future randomized controlled trial requires about 132 subjects per group to have sufficient power to detect statistical differences between treatment and control.

Background

- PICC lines are widely used in the NICU for vascular access and parental nutrition, but their use is complicated by healthcare-associated infections.
 - A silver alginate and maltodextrin containing patch (Algidex™) applied under the standard transparent retention dressing at the PICC exit site has antimicrobial activity and is FDA approved.
 - Preliminary data have demonstrated lack of skin irritation with weekly dressing changes.
 - Efficacy of the Algidex patch in NICU patients is unknown.

Objectives

- To test if the Algidex patch with dressing changes every 2 weeks is safe in the NICU population.
 - To gather efficacy data on infection prevention in preparation for a larger clinical trial.

Methods

- Patients were randomized 3:1 to receive the patch or no patch
 - Dressings and patch were changed every two weeks, and the skin was monitored twice daily by the bedside nurse.
 - All patients and pertinent infection data were followed until PICC discontinuation.

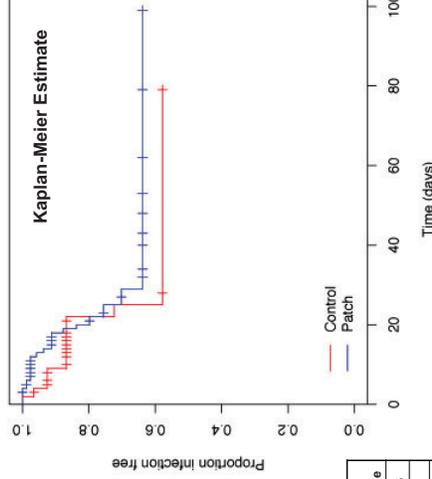
Figure 1: Algidex Patch



No adverse skin changes were noted

Results

Figure 2: Proportion Infection Free Over Time



The '+' symbol indicates when a patient had their PICC removed. The curves drop on days a patient had an infection.

Table 2: Infections per 1,000 PICC days

Control (N=29)	Patch (N=89)	p value
12.3	7.3	0.32

Conclusions

1. The Algidex patch is skin safe for use in the NICU population.
2. CONS remained the most common type of PICC infection.
3. Even with computerized randomization, the patch group had significantly lower gestational age and birth weight.
4. Despite presumed increased risk in the patch group, we observed reduced infection rates.
5. The results warrant a larger trial to measure long-term safety and efficacy.

Acknowledgements

- DeRoyal® for providing patches for the study and a travel grant for MLH.
- The Vanderbilt NICU Research Fund

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 - None of the authors has a financial relationship with DeRoyal.
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Table 1: Demographics (N=100)

	Control (N=29)	Patch (N=89)	p value
Median gestational age (weeks)	36	30	0.003
Median birth weight (g)	2450	1330	0.001
Male	76%	54%	0.04
Median age when PICC placed (days)	4	5	0.38
Median age when PICC removed (days)	18	22	0.10
Median number of PICC days	10	13	0.11
Number of PICC placed			
1	79%	74%	0.85
2	17%	21%	
3	3%	4%	
Dressing changes			
0	62%	55%	0.87
1	21%	28%	
2	10%	9%	
>2	7%	8%	

Table 3: Culture Data

Bacteria Type	Control (N=29)	Patch (N=89)
CONS	3	10
<i>Klebsiella pneumoniae</i>	1	1
<i>Pseudomonas aeruginosa</i>	0	1
<i>Enterococcus spp.</i>	0	1
<i>Candida parapsilosis</i>	1	0
<i>E. coli</i>	1	0